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| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
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| 10/796,336 | 03/08/2004 | | Leone Dall'Asta | 12678/5 | 2011 | |
| 26646 | 7590 | 05/05/2006 | | EXAMINER | | |
| KENYON & | | ON LLP | COVINGTON, RAYMOND K | | | |
| NEW YORK | | 0004 | | ART UNIT | PAPER NUMBER | |
| | | | | 1625 | | |

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | <u> </u> | |
|--|--|--|---|------------------|--|
| | | 10/796,336 | DALL'ASTA ET | DALL'ASTA ET AL. | |
| | Office Action Summary | Examiner | Art Unit | | |
| | | Raymond Covingt | on 1625 | | |
| Period fo | The MAILING DATE of this commun | nication appears on the cover | sheet with the correspondence | address | |
| A SH WHIC - Exte after - If NC - Failu Any | IORTENED STATUTORY PERIOD F CHEVER IS LONGER, FROM THE N ensions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this come of period for reply is specified above, the maximum is ure to reply within the set or extended period for reply reply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b). | MAILING DATE OF THIS CO s of 37 CFR 1.136(a). In no event, hower munication. tatutory period will apply and will expire S y will, by statute, cause the application to | MMUNICATION. ver, may a reply be timely filed IX (6) MONTHS from the mailing date of this become ABANDONED (35 U.S.C. § 133). | | |
| Status | | | | | |
| 1)[🛛 | Responsive to communication(s) file | ed on <u>24 October</u> 2005. | | | |
| · · · · · | , , | 2b)⊠ This action is non-fina | I. | | |
| 3)□ | Since this application is in condition | for allowance except for form | nal matters, prosecution as to | the merits is | |
| | closed in accordance with the pract | ice under <i>Ex parte Quayle</i> , 1 | 935 C.D. 11, 453 O.G. 213. | | |
| Disposit | ion of Claims | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) 22-26,28-46 and 48-61 is/a 4a) Of the above claim(s) is/a Claim(s) is/are allowed. Claim(s) 22-26,28-46 and 48-61 is/a Claim(s) is/are objected to. Claim(s) are subject to restrict | are withdrawn from considera | tion. | | |
| Applicati | ion Papers | · | | | |
| 9) <u> </u> | The specification is objected to by the The drawing(s) filed on is/are Applicant may not request that any objected to specific production is objected to the specific product of the specific pr | : a) accepted or b) objection to the drawing(s) be held ing the correction is required if the | n abeyance. See 37 CFR 1.85(a) drawing(s) is objected to. See 37 | CFR 1.121(d). | |
| Priority ι | under 35 U.S.C. § 119 | | | | |
| a) | Acknowledgment is made of a claim All b) Some * c) None of: 1. Certified copies of the priority 2. Certified copies of the priority 3. Copies of the certified copies application from the Internation | documents have been received documents have been received of the priority documents have been formal Bureau (PCT Rule 17.2(| ved. ved in Application No ve been received in this Nation a)). | al Stage | |
| Attachmen | ••• | 1 | | | |
| 2) 🔲 Notic 3) 🔲 Infor | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (F mation Disclosure Statement(s) (PTO-1449 or er No(s)/Mail Date | PTO-948) P | nterview Summary (PTO-413) Paper No(s)/Mail Date Notice of Informal Patent Application (Fother: | PTO-152) | |

112 REJECTIONS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim s 22-26, 28-42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

The specification teaches adding terephthalic acid to fuming sulfuric acid to obtain a mixture, which is treated with 1,3,5-trioxane as opposed to the claims, which teach reacting formaldehyde, such as 1,3,5-trioxane, with terephthalic acid, and fuming sulfuric acid. See page 4 of the specification.

Claim's 42-46 and 48-61 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the process steps for the synthesis of citalopram, after synthesis of 5-carboxphthalide, is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 42-46 and 48-61 recites the limitation "synthesis of

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citalopram" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim. Claim 22 from which the above claims depend is drawn only to the synthesis of 5-carboxphthalide with no process steps for the synthesis of citalopram, after synthesis of 5-carboxphthalide.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26, 28-42 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6458973. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim common subject matter as follows:

A process for the preparation of 5-carboxyphthalide of formula

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In a reaction by adding formaldehyde and terephthalide acid to fuming sulfuric acid, heating at 120-145° C and isolating 5-carboxyphthalide.

Patentees differ in the use of fuming sulfuric acid containing at least 20% of SO₃ vs. applicants' 25-30%. It is noted that at least 20% includes 25-30%. This is particularly true as all of patentees' examples fall between 25-27%. The use of somewhat different but otherwise analogous process conditions would have been obvious to one of ordinary skill in the art as the results would not have been unexpected. As to the other process parameters note, claims 1-5, 7-23 correspond to applicants' claims 22-26, 28-42 and 44 respectively.

Claims 42-43, 46 and 48-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-67 of U.S. Patent No. 6703516. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim common subject matter as follows: A process for the preparation of citalopram comprising producing 5-carboxyphthalide in a reaction by adding formaldehyde and terephthalide acid to fuming sulfuric acid, heating at 120-145° C and isolating 5-carboxyphthalide.

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Patentees differ in the use of fuming sulfuric acid containing at least 20% of SO₃ vs. applicants' 25-30%. It is noted that at least 20% includes 25-30%. This is particularly true as all of patentees' examples fall between 25-27%. The use of somewhat different but otherwise analogous process conditions would have been obvious to one of ordinary skill in the art as the results would not have been unexpected. As to the other process parameters note, claims 1, 20, 21, 8-17, 4 and 40 correspond to applicants' claims 43, 45-61 respectively.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR

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only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond Covington Examiner Art Unit 1625 Page 6

, BKC

Cecilia J. Tsang
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